STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

1. HEALTH REFORM

COMMENT: The South Carolina Hospital Association (page 187) noted that the health care delivery system will change as a result of health care reform. Because many delivery processes will be redesigned, the Plan must evolve to help create the environment for these changes to occur. There will be more clinical integration between hospitals and physicians and greater emphasis on structuring a continuum of care. The SCHA has recently appointed a Re-Engineering Steering Committee to assist hospitals in creating high performing systems of care and will be willing to share what is learned as their work progresses.

STAFF RESPONSE: We will work with the SCHA and others on the Plan issues to be faced as the healthcare system continues to evolve.

COMMENT: Lynn Bailey (pages 27-28) noted that up to 1 million South Carolinians do not have health insurance, but that by 2014 approximately 600,000 of these people will. These patients currently delay seeking care and rely on emergency departments for coverage, which are a source of about half of all hospital admissions. There will not be enough primary care physicians available when these persons receive insurance coverage so they will continue to use the ERs, at a higher rate because they now have coverage. As a result, hospitals could face overcrowding issues by 2015 due to a resulting increase in admissions through the ERs [**Staff note**: more of her comments are included in the General Hospital Bed Need Comments section].

STAFF RESPONSE: These comments will be addressed in the General Hospital Bed Need Comments section.

COMMENT: Lynn Bailey (pages 28-29) commented on the evolving physician practice model changes. Greenville Hospital System is anticipated to employ more than half of all physicians practicing in the county, in some specialties controlling all providers (pages 31-33). Her concern is the potential conflict of interest because of the influence the hospitals have on the business and economic side of physician practices. She believes that hospital systems that monopolize physicians should be required to obtain a Certificate of Public Advantage (COPA) from DHEC to allow oversight and show that this monopoly is in the public's interests [**Staff note**: additional discussion of this issue are included in the Ambulatory Surgical Facility and Home Health Agency comment sections].

STAFF RESPONSE: COPA has been in place since the mid-1990s. It is a voluntary program that allows for state oversight of integrations/mergers/etc. that otherwise might be subject to Federal Trade Commission (FTC) antitrust investigations. The Department has issued two COPAs, to Palmetto Health and Spartanburg Regional Healthcare. Staff recognizes the concerns expressed, but COPA is a voluntary program and the Department

cannot require providers to apply for one. It would be contingent on a provider such as Greenville Hospital System to determine it is in their best interests to file a COPA to head off any potential federal concerns.

COMMENT: Lynn Bailey (pages 29-30) commented that health care data has been considered proprietary in South Carolina. The Office of Research and Statistics (ORS) has over 30 years of healthcare claims data warehoused but DHEC staff has only limited access to some data elements. More and more health care performance data are becoming available, so there is less justification for keeping information confidential. She asks that the DHEC staff and SHPC request the DHEC Board seek legislative changes to increase data availability.

STAFF RESPONSE: Staff supports this discussion because of the ongoing push of health care reform and quality measures. However, this requires some background information. ORS has had an integrated data system since 1992 that is charged with collecting data to address the following policy issues:

Improving access to health care services.
Containing health care costs.
Maintaining or improving existing quality of care in a cost-effective manner.
Enhancing informed decisions in the selection of health care providers, facilities, and services.
Determining the appropriate types of health care services needed for the State's growing elderly and disabled populations.
Determining the effect of lifestyle, social, environmental, and genetic factors on health.
Evaluating and improving the types of treatment being provided in a wide range of settings.

Source: http://www.ahrq.gov/data/safetynet/bailey2.htm

A number of different agencies share their data with ORS and each has their own rules regarding confidentiality and data release. A significant amount of data has been collected over the years as each unduplicated patient is added to the system. The mechanism for obtaining data is to go through the SC Data Oversight Council. The Council is composed of health care providers, payers, governmental, and business members and oversees what health care data are released through ORS.

The goals of the integrated system are certainly consistent with the Plan and CON programs and staff concurs with Ms. Bailey that there is the potential for additional use of ORS data in health planning. For example, there are currently some data sets where individual facilities are not identified and the data are instead combined by county or region. It would be useful to be able to identify the individual facilities, but to do so might require a re-working of the data release agreements between the providing agency(ies) and ORS.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

2. QUALITY

COMMENT: The South Carolina Hospital Association (pages 187-188) noted that they have developed a comprehensive program focusing on reducing medical errors and hospital-acquired infection, and documenting the best practices for patient care. They indicated their willingness to assist DHEC staff and the SHPC in addressing these areas.

STAFF RESPONSE: Staff acknowledges the offer of future assistance.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

3. STAFFING

COMMENT: The South Carolina Hospital Association (page 188) and Spartanburg Regional Healthcare (page 78) noted that the Draft incorporated a new section on staffing standards. While they recognize that there are projected future shortages of health care workers, they do not support any attempts to create standards tying staffing requirements to sections of the Plan. Each hospital is unique, and such requirements would limit a hospital's flexibility to determine appropriate staffing patterns. Other factors such as the education and experience of professionals, individual needs of the patients, the severity of illness, and the availability of assistive technology also go into the staffing plan. These factors are not reliable as staffing standards to be used in the Plan and CON.

STAFF RESPONSE: The Planning Committee agreed to undertake a study to determine how we could incorporate nursing and technical staffing information into future Plans. Staff has been participating with the Office of Healthcare Workforce Research for Nursing (OHWRN), which is attempting to develop a supply/demand forecast model for nursing and allied technical staff.

We amended the 2009 Joint Annual Reports (JARs) to obtain the baseline numbers for the current number and type of staff, as well as projected future needs, for each type of facility. These numbers have not yet been compiled. We have also not researched staffing guidelines or requirements for the various health professions. As stated in the Draft, we are not in a position to create reliable staffing requirements that could be used as CON standards in the Plan. Therefore, any proposals to incorporate such standards would not be appropriate at this time.

Staff concurs that the concept of specifying staffing criteria as standards in the Plan is problematic, given the variety among facilities and the lack of mandate (i.e. California has legally required nurse to patient ratios). Since the idea of staffing standards is already moot for this Plan, staff recommends re-visiting the issue during the next planning cycle.

At that time we hope to have the existing and projected number of nurses and other staff from the OHWRN study. While it may not be desirable to have specific staffing standards in the Plan, it might be possible to create a standard such as for Rehabilitation [**Staff note**: made up example]:

"South Carolina is projected to have a shortage of xxx of Physical Therapists in 201x. Given this projected shortage of key staff, the applicant must document how they will obtain the necessary staff for this project."

Again, this is a made up example, for possible discussion during the next planning cycle. Other than updating the information on pages I-3-4 of the Draft, we do not recommend any changes to the current Plan.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

4. GENERAL HOSPITAL BED NEED

STAFF NOTICE: The need calculations in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the need calculations for submission to the SHPC. This would also mean changing the years used in the population projections. As a result, the projected need for beds or a particular service could be different from that shown in the Draft Plan.

STAFF RECOMMENDATION: There is an inconsistency between the introductory sentence of Standard (i) on page III-5 and the wording of Standard (i) 2. on page III-6 of the Draft. Rehabilitation beds are not listed in the introductory sentence:

(i) Due to the low utilization and the low capital cost of converting hospital-based nursing home, psychiatric and/or substance abuse beds to general acute care hospital beds, the following policies may apply:

2. Existing general hospitals that have inpatient psychiatric, **rehabilitation**, or substance abuse beds may be allowed to convert these specialty beds to acute care hospital beds, regardless of the projected need for general acute care hospital beds, provided a Certificate of Need is received.

Staff recommends adding rehabilitation beds to the introductory sentence to clarify that all specialty hospital beds can be converted back to general acute beds.

COMMENT: Lexington Medical Center (page 45), Trident Health System (pages 85-86), the South Carolina Hospital Association (page188), MUSC (page 419) and Palmetto Health (page 468) all recommended keeping the bed need methodology as it appears in the Draft.

STAFF RESPONSE: Given the level of support, staff recommends retaining the current bed need methodology in the Plan.

COMMENT: Lynn Bailey (pages 27-28) noted that up to 1 million South Carolinians do not have health insurance, but that by 2014 approximately 600,000 of these people will. These patients currently delay care and rely on emergency departments for coverage, which are a source of about half of all hospital admissions. There will not be enough primary care physicians available when these persons receive insurance coverage so they will continue to use the ERs, at a higher rate because they now have coverage. As a result of increased admissions, hospitals could face overcrowding issues by 2015.

Because she believes that a need methodology based on recent historical utilization is not adequate for the upcoming transitional period, she offered two potential adjustments to the bed need methodology:

1) Project a bed need range of +/- 10% rather than an exact number.

2) Create a new category of temporary short term acute care beds. Hospitals could apply for additional beds even in areas that did not show a need. These beds could be added for 3-5 years to accommodate the transition of health reform. A hospital would have to apply for another CON to make these beds permanent after five years.

STAFF RESPONSE: Staff does not recommend accepting either of these adjustments. A 10% range does not appear feasible, because we already have a provision in the Plan that allows a hospital showing a positive bed need to add the greater of the actual need or 50 beds in order to build a more economical unit. The only time this proposal would be of use would be a situation where a hospital is projected to need greater than 50 beds; in the Draft, only Palmetto Richland would benefit.

The second proposal is problematic for several reasons. First, as noted above, hospitals showing a positive bed need can apply for up to 50 beds, so there is already built-in flexibility to add beds beyond the number projected as needed.

Second, additional capacity currently exists in many hospitals. Almost half the hospitals in the state had occupancy rates below 50% in 2008, while over 2/3 were below 60%. The bed need methodology projects need for seven years into the future, with 65% being the lowest occupancy factor in the calculations. Given the current and projected excess bed capacity, along with the potential short term use and expense required for construction, it is not clear that hospitals would be willing to invest the money for such a proposal. As she states (page 28) "…no rational hospital or health service provider will request a bed or service increases [sic] they don't need and can't finance." Staff is not convinced that hospitals with relatively low occupancy rates are going to have the financial wherewithal or interest in constructing additional temporary capacity.

There are no licensing standards to differentiate "short term" beds from other general acute beds. This proposal would require the Department to create and maintain a separate inventory system for these beds, track their utilization for up to five years (from date of CON or date of licensure), and then require the hospital to go back through CON review a second time if they want to make the beds "permanent." We would also have to somehow account for the utilization in these beds in the bed need methodology that would require the hospitals to differentiate their utilization of these beds on the JAR. In addition, as a matter of semantics, a potentially six+ year process appears to go beyond what staff would normally consider to be a "temporary" solution.

Finally, we received no indications from the SCHA or individual hospitals that they believe that bed need should be increased because of the potential impacts of health reform. Therefore, staff cannot endorse these proposed revisions.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

5. OBSTETRICAL AND NEONATAL SERVICES

STAFF NOTICE: The need calculations in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the need calculations for submission to the SHPC. This would also mean changing the years used in the population projections. As a result, the projected need for beds or a particular service could be different from that shown in the Draft Plan.

COMMENT: Spartanburg Regional Healthcare (page 78) supported the proposed change in need methodology for Neonatal Intensive Care Unit (NICU) bassinets. Regional Perinatal Centers (RPCs) serve a number of Low and Very Low Birthweight (LBW/VLBW) babies and need the ability to increase their capacity based on demonstrated need. However, because of the time lapse between Plans, they also requested that a provision be added to the Plan allowing any RPC to apply for additional NICU bassinets if the need can be documented from either the most recent Joint Annual Reports (JARs) or a "rolling" 12-month period.

COMMENT: Roper St. Francis Healthcare (page 65) also supported the change to an institution-specific rather than regional need methodology.

STAFF RESPONSE: A limitation of the methodology in the current 2008-09 Plan was the timeliness of the data. We only had 2005 data available for doing need calculations in 2008. The proposal to allow use of more current data than what is published in the Plan does have some precedence. For example, we can consider an application for a new Ambulatory Surgical Facility in a county if we have received the most current JARs from the existing providers. We also require applicants to use the "most recent year" of data for services such as cardiac catheterization and radiotherapy.

However, staff does not support the concept of a "rolling" 12-month period of data. This opens the opportunity for applicants to pick-and-choose the most favorable time period of utilization data for their project. Not all facilities use the exact same reporting period for JARs (about half of the hospitals use the calendar year while most of the rest use the Federal Fiscal Year of October 1 – September 30), but these are close enough to allow for a consistent regional or statewide analysis of the data. We could not create this provision in one section of the Plan without allowing it in other sections as well, which could result in additional data requests to other providers so staff can compare their utilization with the "rolling" data from the applicant.

COMMENT: Bon Secours St. Francis Health System (page 358) stated that it was unclear from the proposed methodology how a new provider can demonstrate need. They suggested that a methodology be adopted that would allow existing providers to expand if

their own utilization indicates a need for additional capacity while maintaining a methodology that would allow a new provider to demonstrate need.

STAFF RESPONSE: The proposed new methodology is a significant change from the methodology that has been used in the Plan for a number of years. The previous methodology projected need on a perinatal region basis. There were several reasons why staff recommended the change. First, the ratios used in the calculations dated back to 1981 and were no longer suggested by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists. Second, the data regarding the number of Low Birth Weight (LBW) and Very Low Birth Weight (VLBW) babies were out of date. For the 2008-2009 Plan, 2005 births data were the most currently available. Third, the projected numbers of births were consistently lower than the actual numbers. For these reasons, we determined that the methodology was not accurately matching the current needs of the providers.

The proposed new methodology is facility-specific and is based on the most current actual utilization of the Regional Perinatal Centers (RPCs) and Level III nurseries. The need methodology for Intermediate Bassinets was similarly revised and is calculated based on the utilization of each Level II nursery. Staff experimented but was unable to come up with a satisfactory methodology that would incorporate Bon Secours St. Francis Health System's request. Staff recommends that this issue be revisited next planning cycle.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

6. LONG TERM ACUTE CARE HOSPITALS

COMMENT: The National Association of Long Term Hospitals (NALTH) (pages 169-185) proposed a number of revisions to the LTACH section of the Draft. North Greenville Hospital (page 43), Spartanburg Hospital for Restorative Care (pages 53 and 55) and Spartanburg Regional Healthcare (page 79) submitted comments supporting these recommendations. First, they expressed concern that the definition of an LTACH including the phrase "...and have an average length of stay of 25 days or longer" (III-31) could be construed as requiring a minimum 25 day length of stay for all patients. They note that the 25 day average ALOS does not apply to non-Medicare patients. They recommended amending the definition of an LTACH as "a hospital with an average Medicare inpatient length of stay of greater than 25 days, including all covered and non-covered days of stay of Medicare patients." This definition was taken from part of the Federal definition.

STAFF RESPONSE: Staff believes the use of the word "average" is self-evident that not all patients will stay for a minimum of 25 days. However, staff recommends revising the definition as requested.

COMMENT: The NALTH noted that the Patient Protection and Affordability Act of 2010 ("Health Reform") allows pilot programs where the Secretary of DHHS has waived compliance with the 25 day Medicaid ALOS requirement.

STAFF RESPONSE: Staff recommends adding a statement to this effect in the first paragraph of III-31.

COMMENT: The NALTH commented that the first paragraph includes the statement: "These patients require up to 3 hours per day of rehabilitative treatment..." They recommend deleting this statement, as it is not a CMS condition.

STAFF RESPONSE: This wording came from the Mississippi definition of an LTACH that we received in 2006 when we canvassed other states' CON programs: "A long-term care hospital shall provide chronic or long-term medical care to patients who do not require more than three (3) hours of rehabilitation or comprehensive rehabilitation per day." Another state had a standard: "The applicant should provide assurance that the projected caseload will require no more than three (3) hours per day of rehabilitation." We're not sure where the 3 hours standard originally came from, but apparently multiple states have used some variation of it. However, staff is not opposed to deleting this statement if it is not required as a CMS condition.

COMMENT: The NALTH recommended revising the paragraph on III-31 referring to the "25% payment threshold" for LTACHs to be consistent with 42 CFR 412.534(c)(1).

STAFF RESPONSE: The wording in the Draft came from journal articles at that time. The federal guidelines recommended regarding the "25% rule" are three pages long and contain varying treatments of co-located hospitals, urban single, MSA-dominant, and rural hospital LTACHs. Staff sees no reason to incorporate this much detail into the Plan and instead recommends amending the paragraph as follows:

> LTACHs have their own Prospective Payment System (PPS). In 2006, CMS established a "25% payment threshold policy" for **LTACHs**. ~~hospitals within hospitals. If the LTACH's Medicare discharges exceed 25% from the host hospital, the LTACH would be paid the lesser of the otherwise payable amount under the LTACH PPS or the equivalent amount that Medicare would have paid under the Acute Care Hospital Inpatient PPS.~~ **For the current details of the policy consult 42 CFR 412.534(c)(1).**

COMMENT: The NALTH noted that, as a result of Health Reform, the moratorium on new LTACHs and the period of relief from the 25% Rule were extended for a further two years.

STAFF RESPONSE: This information will be updated.

COMMENT: The NALTH noted that the final payment increase for 2010 was actually 2.0% rather than the proposed 2.2% referenced in the Draft.

STAFF RESPONSE: The proposed percent came from journal articles and will be revised to reflect the final budget numbers.

COMMENT: North Greenville Hospital (page 43), Spartanburg Hospital for Restorative Care (page 53), Spartanburg Regional Healthcare (page 79), and the SCHA (page 188) objected to the following Quality language on page III-33:

> The DHEC Hospital Acquired Infections (HAI) report includes a standardized Central Line Associated Blood Stream Infections (CLABSI) ratio for LTACHs. All South Carolina LTACHs should be lower than or not different from their statistically expected ratios. For temporary central lines in 2009, Intermedical Hospital had statistically significantly fewer CLABSIs than projected. The Regency Hospitals in Florence and Greenville were within their expected ranges, while kindred Hospital, North Greenville LTACH and Spartanburg Hospital for Restorative Care had higher than expected rates. Source:
>
> http://www.scdhec.gov/health/disease/hai/docs/Table%207.%20Long%20Term%20Acute%20Care%20Unit.pdf

They noted that this was the only Quality section in the Draft where the performance of specific facilities was reported. For example, the Nursing Home section has proposed quality measures but does not list the performance of individual facilities. Infection rates are influenced by a number of factors and can change over time. Given the two year

planning cycle, the information presented could present an outdated and inaccurate view of the infection rates in South Carolina's LTACHs. Spartanburg Hospital for Restorative Care (pages 53-54) and Spartanburg Regional Healthcare (page 79) proposed the following alternative language for this section:

> The DHEC Hospital Acquired Infections (HAI) report includes a standardized Central Line Associated Blood Stream Infections (CLABSI) ratio for LTACHs. Each LTACH is compared to the national standard population of hospitals entering HAI data into the National Healthcare Safety Network (NHSN) database. The Standardized Infection Ratio (SIR) is a summary measure used to compare the CLABSI experience among a group of reported locations to that of a standard population. It is the observed number of infections divided by the expected (predicted) number of infections. For HAI reports, the standard population comes from NHSN data reported from all hospitals using the system in the United States. The "expected" number of infections is based on historical data for those procedures at the national level. All South Carolina LTACHs should be lower than, or not different from, their statistically expected ratios. The report is accessible online at: http//www.scdhec.gov /health/disease/hai/docs/Table%207.%20Long%20Term%20Acute%20Care%20Unit.pdf. The Department may use the HAI report in evaluating a CON application for additional LTACH beds at an existing facility.

STAFF RESPONSE: Staff recommends amending the wording on III-33 as follows:

> The DHEC Hospital Acquired Infections (HAI) report includes a standardized Central Line Associated Blood Stream Infections (CLABSI) ratio for LTACHs. **Each LTACH is compared to the national standard population of hospitals entering HAI data into the National Healthcare Safety Network (NHSN) database. The Standardized Infection Ratio (SIR) is a summary measure used to compare the CLABSI experience among a group of reported locations to that of a standard population. It is the observed number of infections divided by the expected (predicted) number of infections. For HAI reports, the standard population comes from NHSN data reported from all hospitals using the system in the United States. The "expected" number of infections is based on historical data for those procedures at the national level**. All South Carolina LTACHs should be lower than, or not different from, their statistically expected ratios. ~~For temporary central lines in 2009, Intermedical Hospital had statistically significantly fewer CLABSIs than projected. The Regency Hospitals in Florence and Greenville were within their expected ranges, while kindred Hospital, North Greenville LTACH and Spartanburg Hospital for Restorative Care had higher than expected rates. Source:~~ The report is accessible online at: http//www.scdhec.gov /health/disease/ hai/docs/Table%207.20Long%20Term%20Acute%20Care%20Unit.pdf. **The Department may use the HAI report in evaluating a CON application for additional LTACH beds at an existing facility.**

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

7. CRITICAL ACCESS HOSPITALS

STAFF RECOMMENDATION: Page III-35 lists a number of additional hospitals that could potentially participate in the Critical Access Hospital program based on their Average Daily Census (ADC). Staff has determined that some of these listed facilities may not actually be eligible for CAH status because they are either for-profit or are too close to other hospitals. Staff recommends the following changes to this section:

> The following facilities in South Carolina are designated as CAHs, **although there are other hospitals that could potentially be eligible**:
>
> Abbeville Memorial Hospital
> Allendale County Hospital
> Edgefield County Hospital
> Fairfield Memorial Hospital
> Williamsburg Regional Hospital
>
> ~~Based on their 2008 Average Daily Census (ADC), the following hospitals in South Carolina could potentially participate in the CAH program: Cannon Memorial (10.3), McLeod Darlington (24.8), Lake City Community (11.0), Marlboro Park (14.5), Bamberg County Memorial (5.8), Barnwell Hospital (10.0), Hampton Regional (8.4), and Coastal Carolina Medical Center (10.4).~~

COMMENT: Williamsburg Regional Hospital (pages 203-204) requested a specific policy that would allow any of the five Critical Access Hospitals (CAHs) in South Carolina to establish a Distinct Part Geropsychiatric and/or Acute Rehabilitation Unit outside the normal CON standards for psychiatric or rehabilitation beds. Under federal guidelines, a CAH can have up to 25 acute/swing beds and up to 10 bed Distinct Part Geropsychiatric and/or Acute Rehabilitation Units, with favorable Medicare reimbursement. These programs have been successful in other southern states. [**Staff Note**: These and the following comments will also appear in the Psychiatric and Rehabilitation Staff Response sections].

COMMENT: Allendale County Hospital (page 158) supported the above proposal. Allendale is also a CAH and is an essential provider to a needy population. It is important to the future delivery of health care that the hospital has the opportunity to implement such programs. With limited resources it is challenging to engage in a CON process.

COMMENT: Greenwood Rehabilitation Hospital (pages 164-165) opposed the Williamsburg proposal. Inpatient rehabilitation facilities care for critically ill patients requiring multi-disciplinary treatment. CMS issued new stringent guidelines in January 2010 that CAHs are unlikely to meet. CAHs by definition are small, rural hospitals unlikely to have or to recruit the clinical staff and physicians needed, and are unlikely to

treat the number of patients with the specified conditions requiring rehabilitation. The proposed change would allow increased reimbursement but a 10 bed unit would not be profitable. Patient quality would suffer by understaffed and inexperienced clinical personnel. Allowing the proliferation of small, isolated units is counter-intuitive.

COMMENT: AnMed Health Rehabilitation Hospital (page 416) opposed the CAH proposal. The existing acute rehabilitation providers serve the state and aren't running at the capacity required to generate additional bed need. Acute rehabilitation services require technology, and CMS requires trained rehabilitative physicians and licensed staff assessments. The standard of care should not be decreased to allow CAHs to increase their census.

COMMENT: The SCHA (pages 188-189) opposed the proposal to allow special consideration for CAH distinct part units because of the precedence it would set. They offered to work with the CAHs through their Small & Rural Hospital Council to identify opportunities that might enhance the services they provide but that would not establish this type of precedence.

COMMENT: A joint statement was received from Three Rivers Behavioral Health, Springbrook Behavioral Health System, Lighthouse Care Center of Conway, Palmetto Lowcountry Behavioral Health, and Carolina Center for Behavioral Health (pages 37-38) opposing the Critical Access Hospital proposal. There is no distinction made in the Plan between geropsychiatric and other psychiatric services. Special waivers given to distinct type hospitals will erode the integrity of the Plan and negatively impact existing providers. The Plan has a proven bed need methodology and should not permit special exceptions to maintain its integrity.

STAFF RESPONSE: Staff recommends that the SHPC not accept the Distinct Part Geropsychiatric proposal. Only 60% of the psychiatric providers (12/20) operated at greater than 50% of occupancy in 2008 (IV-1), so it appears there is additional capacity available within the existing providers. In addition, it is not clear that CAHs would be able to obtain the psychiatrists and other related required mental health staff. Not mentioned in the comments were the potential expenses required to bring the beds up to current psychiatric licensing and building standards, which are more stringent in some areas than for general acute beds. Finally, staff notes that the SCHA has offered to identify other opportunities to assist these hospitals rather than through creation of exceptions to the accepted methods for bed allocation.

STAFF RESPONSE: Staff also recommends that the SHPC not accept the Distinct Part proposal for Acute Rehabilitation Units. There are currently 16 rehabilitation providers in the state, with at least three in each Inventory Region, so they are accessible to the majority of the state. Given the more stringent CMS requirements, it is not clear that CAHs would be able to obtain the needed physicians and other staff, as well as treat enough patients that meet these requirements. The potential upfit and equipment costs to create a rehab unit were not discussed in the comments. As noted above, the SCHA has offered to assist these hospitals to identify other opportunities.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

8. PEDIATRIC LONG TERM ACUTE CARE HOSPITALS

COMMENT: Post Acute Partners (pages 57-60) submitted a proposal for a Long Term Acute Care Facility for Severely Impaired Children. These are for children who no longer require acute care hospitalization but are not able to return to their homes. Examples include: partial drownings, asthma, car accidents, neurological injuries, premature births and abuse. Post Acute Partners currently operates five such facilities in Pennsylvania. The proposed facility would partner with one of the Children's Hospitals in South Carolina. They received a recent estimate that there are four to five patients in each of the Children's Hospitals at any time that could benefit from this proposed project.

COMMENT: Palmetto Health (page 468) operates one of the four Children's Hospitals in South Carolina and believes that many of their patients could benefit from such a facility. They support the inclusion of the proposal in the Draft and believe the proposed review standards are appropriate.

COMMENT: Greenville Hospital System (page 407) stated they have no objections to the Pediatric LTACH proposal in the Draft Plan.

STAFF RESPONSE: Accepted as information.

STAFF COMMENT: During the North Charleston public hearing, the question was asked whether Post Acute Partners would abide by the proposed Standard 6 on page III`-37, which prevents a Pediatric LTACH from converting to a general hospital. Mr. Carner, on behalf of Post Acute Partners, stated that his company had no desire to create a general hospital, so if the Pediatric LTACH venture proved unsuccessful, they would close the facility and not seek to have it re-licensed as a general acute hospital. This acknowledgement does not appear in the written comments received from Post Acute Partners.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

9. PSYCHIATRIC SERVICES

STAFF NOTICE: The need calculations in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the need calculations for submission to the SHPC. This would also mean changing the years used in the population projections. As a result, the projected need for beds or a particular service could be different from that shown in the Draft Plan.

COMMENT: The SCHA (page 189), Mental Health America of South Carolina (pages 160-162), the National Alliance on Mental Illness South Carolina (pages 193-194), and Palmetto Health (pages 468-469) supported changing the need methodology back to using 75% of the statewide average number of beds per 1,000 population in the calculations. Adding additional beds will redistribute the current patient load and make it harder for the existing providers to succeed. The major problem is with uninsured or indigent patients for whom the Department of Mental Health (DMH) is no longer able to fund services.

COMMENT: A joint statement was received from Three Rivers Behavioral Health, Springbrook Behavioral Health System, Lighthouse Care Center of Conway, Palmetto Lowcountry Behavioral Health, and Carolina Center for Behavioral Health (pages 36-37) opposing the proposed change to 100% of the statewide average. The change in the methodology is unwarranted and will adversely impact the current providers. The Draft Plan (IV-1) indicates that six of the 20 providers in the state operated below 40% occupancy in 2008 and eight of the 20 were below 50%. This indicates that many currently licensed beds are not operational, and artificially expanding the number of beds will only exacerbate the problem. There is a statewide problem of patients being warehoused in emergency rooms awaiting transfer. While not suggesting it will solve the crisis, it was noted that hospitals can contract with DMH for crisis stabilization services in their existing beds without having to go through CON. Finally, the Plan makes no distinction between geropsychiatric and other psychiatric services, so the assertion that there is a growing need for psychiatric services for the elderly is unsubstantiated.

COMMENT: Spartanburg Regional (page 80) supports additional community psychiatric beds, but like the commenters listed above, believes the greatest need is for involuntary beds to serve the mentally ill. They are currently being held in Emergency Centers for extended periods of time, because DMH cannot provide care.

STAFF RESPONSE: Based on the responses received, there was no support for amending the need methodology to 100% of the statewide average use rate. Staff recommends the following revision to Standards 2 and 3 on page IV-2 of the Draft Plan:

2. The bed need methodology takes the greater of the actual utilization of the facilities in the service area or **75% of** the statewide average beds per 1,000 population to project need.

3. For service areas without existing psychiatric units and related utilization data, **75% of** the statewide average beds per 1,000 population was used in the projections.

COMMENT: Williamsburg Regional Hospital (pages 203-204) requested a specific policy that would allow any of the five Critical Access Hospitals (CAHs) in South Carolina to establish a Distinct Part Geropsychiatric Unit outside the normal CON standards for psychiatric beds. Under federal guidelines, a CAH can have up to 25 acute/swing beds and up to 10 bed Distinct Part Geropsychiatric Unit, with favorable Medicare reimbursement. These programs have been successful in other southern states. [**Staff Note**: These and the following comments will also appear in the Psychiatric and Rehabilitation Staff Response sections].

COMMENT: Allendale County Hospital (page 158) supported the Williamsburg proposal. Allendale is also a CAH and is an essential provider to a very needy population. It is important to the future delivery of health care that the hospital has the opportunity to implement such programs. With limited resources it becomes challenging to engage in a full blown CON process.

COMMENT: The SCHA (pages 189-190) opposed the proposal to allow special consideration for CAH distinct part units because of the precedence it would set. They offered to work with the CAHs through their Small & Rural Hospital Council to identify opportunities that might enhance the services they provide but that would not establish this type of precedence.

COMMENT: A joint statement was received from Three Rivers Behavioral Health, Springbrook Behavioral Health System, Lighthouse Care Center of Conway, Palmetto Lowcountry Behavioral Health, and Carolina Center for Behavioral Health (pages 37-38) opposing the Critical Access Hospital proposal. There is no distinction made in the Plan between geropsychiatric and other psychiatric services. Special waivers given to distinct type hospitals will erode the integrity of the Plan and negatively impact existing providers. The Plan has a proven bed need methodology and should not permit special exceptions to maintain its integrity.

STAFF RESPONSE: Staff recommends that the SHPC not accept the Critical Access Hospital proposal. Staff previously recommended reducing the bed need calculations back to 75% of the statewide use rate because of the current low utilization. It appears there is additional capacity available within the existing providers. In addition, it is not clear that CAHs would be able to obtain the psychiatrists and other related required mental health staff. Not mentioned in the comments were the potential expenses required to bring the beds up to current psychiatric licensing and building standards, which are more stringent in some areas than for general acute beds. Finally, staff notes that the

SCHA has offered to identify other opportunities to assist these hospitals rather than through creation of exceptions to the accepted methods for bed allocation.

STAFF RECOMMENDATION: There are no Quality standards for psychiatric services in the Draft Plan. In July, staff became aware of a new initiative to establish core quality measures for behavioral health providers, and recommends that the following new section on Quality be inserted after the Certificate of Need standards on page IV-2:

> **Quality**
>
> The Hospital-Based Inpatient Psychiatric Services (HBIPS) project grew from a partnership among the National Association of Psychiatric Health Systems, the National Association of State Mental Health Program Directors, the American Psychiatric Association and the Joint Commission. The HBIPS core measures focus on critical issues that affect the course of a patient's hospitalization, such as admissions screening and having a coordinated plan for continuity of treatment. Other measures address the use of anti-psychotic medications and the reduction in the use of restraints and seclusion. Collection and reporting of these measures are expected to become mandatory starting in 2013, and pilot testing of pay-for-performance measures by 2016. All South Carolina hospitals that offer inpatient psychiatric services should support the HBIPS project and be in compliance with its core measures.

STAFF RECOMMENDATION: Currently, the "Relative Importance of Project Review Criteria" section is located on IV-4 after B. State Mental Health Facilities. These are required for all sections of the Plan with CON criteria and should be re-located after the new Quality section referenced above (i.e. before the State Mental Health Facilities section).

STAFF EXPLANATION: The William J. McCord Adolescent Facility is a facility that has provided substance abuse treatment for adolescents statewide for a number of years. In the Draft Plan the facility is discussed on pages VI-4-5. Because of changes in reimbursement, McCord received a CON to convert from a specialized hospital with 15 substance abuse beds to one with 15 psychiatric beds restricted primarily for the provision of alcohol and drug abuse treatments for adolescents. The mission of the facility hasn't changed, but the bed classification had to be changed in order for McCord to continue receiving reimbursement. Staff has added a new Section 3 explaining the McCord change in status on page IV-4 of the Draft Plan.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

10. REHABILITATION FACILITIES

STAFF NOTICE: The need calculations in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the need calculations for submission to the SHPC. This would also mean changing the years used in the population projections. As a result, the projected need for beds or a particular service could be different from that shown in the Draft Plan.

COMMENT: Parker Poe (pages 363-364) had questions regarding how the need formula was calculated.

STAFF RESPONSE: The staff reply is included on those pages.

COMMENT: Williamsburg Regional Hospital (pages 203-204) requested a specific policy that would allow any of the five Critical Access Hospitals (CAHs) in South Carolina to establish a Distinct Part Acute Rehabilitation Unit outside the normal CON standards for rehabilitation beds. Under federal guidelines, a CAH can have up to 25 acute/swing beds and up to 10 bed Distinct Part Acute Rehabilitation Units, with favorable Medicare reimbursement. These programs have been successful in other southern states. [**Staff Note**: These and the following comments will also appear in the Critical Access Hospital Staff Response section].

COMMENT: Allendale County Hospital (page 158) submitted a comment supporting the Williamsburg proposal. Allendale is also a CAH and is an essential provider to a very needy population. It is important to the future delivery of health care that the hospital has the opportunity to implement such programs. With limited resources it becomes challenging to engage in a full blown CON process.

COMMENT: Greenwood Rehabilitation Hospital (pages 164-165) opposed the Williamsburg proposal. Inpatient rehabilitation facilities care for critically ill patients requiring multi-disciplinary treatment. CMS issued new stringent guidelines in January 2010 that CAHs are unlikely to meet. CAHs by definition are small, rural hospitals unlikely to have or to recruit the clinical staff and physicians needed, and are unlikely to treat the number of patients with the specified conditions requiring rehabilitation. The proposed change would allow increased reimbursement but a 10 bed unit would not be profitable. Patient quality would suffer by understaffed and inexperienced clinical personnel. Allowing the proliferation of small, isolated units is counter-intuitive.

COMMENT: AnMed Health Rehabilitation Hospital (page 416) opposed the CAH proposal. The existing acute rehabilitation providers serve the state and aren't running at the capacity required to generate additional bed need. Acute rehabilitation services

require technology, and CMS requires trained rehabilitative physicians and licensed staff assessments. The standard of care should not be decreased to allow CAHs to increase their census.

COMMENT: The SCHA (pages 188-189) opposed the proposal to allow special consideration for CAH distinct part units because of the precedence it would set. They offered to work with the CAHs through their Small & Rural Hospital Council to identify opportunities that might enhance the services they provide but that would not establish this type of precedence.

STAFF RESPONSE: Staff recommends that the SHPC not accept the Distinct Part proposal for Acute Rehabilitation Units. There are currently 16 rehabilitation providers in the state, with at least three in each Inventory Region, so they are accessible to the majority of the state. Given the more stringent CMS requirements, it is not clear that CAHs would be able to obtain the needed physicians and other staff, as well as treat enough patients that meet these requirements. The potential upfit and equipment costs to create a rehab unit were not discussed in the comments. As noted above, the SCHA has offered to assist these hospitals to identify other opportunities to enhance their services.

COMMENT: Laurens County Health Care System (pages 70-71), John Heydel, former President and CEO of Self Regional Healthcare (pages 155-156), and Self Regional Healthcare (pages 360-361) submitted a proposed amendment to the Draft allowing rehab facilities with licensed nursing home beds to convert them to rehab regardless of the projected need:

> Rehabilitation facilities that have licensed nursing home beds within the facility may be allowed to convert these nursing home beds to rehabilitation beds within the existing facility provided that the rehabilitation facility can document an actual need for these additional rehabilitation beds in its facility. A rehabilitation hospital that can demonstrate a need for additional rehabilitation beds may be allowed to convert nursing home beds to rehabilitation beds regardless of the projected need of rehabilitation beds in the service area.

Under the current bed need methodology, a hospital may be operating at a high occupancy rate but show no need for additional beds. There are three facilities that could potentially benefit from the proposed amendment. It would help alleviate over-crowding at some facilities without leading to an influx of unneeded beds. It is also not without precedence. The proposal is based on similar language in the Draft (III-5-6) allowing general acute hospitals to convert nursing home, psychiatric, substance abuse and rehabilitation beds to acute care beds. The Plan already recognizes the benefit of allowing facilities to convert under-utilized specialty beds.

COMMENT: A total of 24 physicians from the Montgomery Center for Family Medicine at Self Regional Healthcare submitted letters of support for the proposed amendment to the Plan (pages 206-207). They noted that Greenwood Regional Rehabilitation Hospital had submitted the initial request for the provision but that it had

not been included in the Draft. They indicated that their practices depended upon the services provided at GRRH and that it was becoming more difficult to place their patients at the facility as its utilization increases. Requiring patients to seek services out of area would increase travel significantly and place a burden on the families of patients. Similar letters of support were received from Dr. Carlos Manalich from Greenwood Internal Medicine (page 196) and Dr. Clifford Mondo from Palmetto Medical Rehabilitation (page 198).

STAFF RESPONSE: This proposal initially made by GRRH was included in the staff synopsis sent to the Committee prior to the SHPC meeting. Their proposal was motivated by their situation. The facility's occupancy rate for 2008 was 67.6% (V-1). The facility was licensed in late 2007, so their 2008 JAR reflected lower utilization due to start-up (i.e. facilities don't open and become fully occupied the first day) than what they were currently experiencing. As a result, the bed need calculations showed no need in their service area and this could potentially prevent them from adding beds until the next Plan [**Staff Note**: there was actually an Excel spreadsheet error in the bed need calculations on V-3; instead of an excess of six beds, there was in reality a need for one additional bed in the service area]. However, GRRH also has 12 nursing home beds with a 2008 occupancy rate of 57.7% (XIII-19). Because the need methodology was not going to show a positive need, despite the more current higher utilization, GRRH proposed allowing the conversion of nursing home beds to rehab beds, similar to the provisions already in the Plan allowing the conversion of nursing home and specialty hospital beds to general acute beds.

This proposal could impact a maximum of three facilities, although it is likely of only being applied in the case of GRRH. It is true that we allow the general acute bed conversions regardless of the bed need. However, there is opposition to the concept of allowing specialty beds beyond what is projected as needed in the Plan. Staff is admittedly ambivalent about this proposal. We supported it in the staff synopsis but the SHPC elected to not include it in the Draft Plan sent for public comment. If we are able to utilize 2009 data in the final calculations, it is anticipated that a greater need for beds will be shown in the GRRH service area, which may alleviate their concerns about the Plan showing outdated utilization and need projections.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

11. ALCOHOL AND DRUG ABUSE SERVICES

STAFF NOTICE: The need calculations in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the need calculations for submission to the SHPC. This would also mean changing the years used in the population projections. As a result, the projected need for beds or a particular service could be different from that shown in the Draft Plan.

STAFF EXPLANATION: The William J. McCord Adolescent Facility is a facility that has provided substance abuse treatment for adolescents statewide for a number of years. In the Draft Plan the facility is discussed on pages VI-4-5. Because of changes in reimbursement, McCord received a CON to convert from a specialized hospital with 15 substance abuse beds to one with 15 psychiatric beds restricted primarily for the provision of alcohol and drug abuse treatments for adolescents. The mission of the facility hasn't changed, but the bed classification had to in order to continue receiving reimbursement. Staff has amended the references to McCord on pages VI-4-5 and added an explanation of the McCord change in status in the psychiatric section of the Draft Plan.

STAFF RECOMMENDATION: Because McCord is no longer licensed as an alcohol and drug abuse facility, staff recommends deleting Standard 8 on page VI-5 of the Draft.

COMMENT: Parker Poe (page 9) questioned whether the Methadone section would be dropped from the Draft Plan (pages VI-7-8), because these facilities were deleted from the definition of a health care facility in the recent Certificate of Need law revisions.

STAFF RESPONSE: Because these are no longer defined as a health care facility by law, staff recommends deleting section VI. F. Narcotic Treatment Programs (pages VI-7-8) in its entirety from the Alcohol & Drug Abuse Facilities component of the Plan.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

12. RESIDENTIAL TREATMENT FACILITIES FOR CHILDREN & ADOLESCENTS

COMMENTS: Parker Poe (pages 428-450) requested that the Department re-incorporate a bed need methodology for RTF beds.

COMMENTS: A joint statement was received from Three Rivers Behavioral Health, Springbrook Behavioral Health System, Lighthouse Care Center of Conway, Palmetto Lowcountry Behavioral Health, and Carolina Center for Behavioral Health (pages 39-41) in support of the Parker Poe request. A similar statement of support was received from the National Alliance on Mental Illness South Carolina (page 194).

STAFF RESPONSE: Staff is not opposed to the concept of a bed need methodology since we used to have one. However, this issue requires an explanation because of the unique reason for why the bed need methodology was deleted. A brief chronology:

RTF beds were first inventoried in the Plan in 1991, and the need methodology was always based on a projected number of beds for the projected population. Initially need was projected statewide, then later by the four Inventory Regions. In the 2004-2005 Plan, we used a standard of 41.1 beds per 1,000 population age six-21. We had 376 existing beds and projected a need for a total of 403 beds, or 27 additional beds statewide.

In State Fiscal Year 2007-2008, Budget Proviso 8.35 was passed (page 450), which allowed High Management Group Homes licensed by DSS to convert to an RTF without having to go through the CON process and regardless of any projected need. The only requirement relative to CON was that they had to request an exemption from the Department prior to January 1, 2008.

By the proviso deadline we received exemption requests for 473 beds, which would more than double the existing number of beds and far exceed the projected need. However, the proviso did not set a deadline by which the beds had to be licensed as RTF beds and there was no guarantee that any/all of these beds would actually become licensed. Therefore, when we developed the RTF section of the 2008-2009 Plan, we removed the bed need methodology and instead left it to any applicants to justify that their proposed beds were needed. This is also the language that appears in the current Draft (VII-3).

Staff proposed to continue with the existing standards in the Draft and not calculate a bed need. However, given the amount of support for re-establishing a bed need methodology, and lack of support expressed for the current standards, staff is willing to re-institute such a methodology into the Plan.

One difficulty in creating a bed need methodology is the open-ended nature of the proviso exemption from CON. As of this date, only 333 of the potential 473 beds

exempted under the proviso have actually been licensed, leaving up to a potential 140 additional beds in limbo:

Facility	# Beds Proposed	#Beds Licensed	#Beds Not Licensed
Pinelands Group Home	40	0	40
Carolina Children's Home	30	20	10
Willowglen Academy	54	40	14
Generations – Bridges	10	0	10
Generations – Horizons	20	0	20
Lighthouse of Conway	60	14	46

Because of this uncertainty, staff contacted these providers to determine their intent to implement the remaining beds provided for in their exemptions. As a result of the survey, it is anticipated that 82 of the potential 140 additional beds will eventually be licensed:

Facility	Potential Additional Beds	#Beds To Be Licensed	#Beds Not Licensed
Pinelands Group Home	40	28	12
Carolina Children's Home	10	10	0
Willowglen Academy	14	14	0
Generations – Bridges	10	10	0
Generations – Horizons	20	10	0
Lighthouse of Conway	46	0	46

We currently have almost twice as many RTF beds as were projected as needed under the old methodology. This could mean either: 1) the old methodology was inaccurate because we have twice as many beds as were shown as needed; or 2) the old methodology was accurate but because of the budget proviso we have more beds than we need.

Utilization was high for the existing providers in 2008, with seven RTFs having occupancy rates close to or above 90% (VII-1). The overall rate was 85.6%. However, these numbers did not include the group homes converted via the proviso. We have at least partial-year utilization for a number of these new facilities in 2009. Even with a significant increase in the number of licensed beds, the overall state occupancy rate was 80.0%. Anecdotal evidence we have received from several providers is that utilization is decreasing in 2010. Almost all of these patients qualify for Medicaid, but as the budget has been cut, the amount of match money used to fund this care has significantly decreased, so patients are being maintained in less-costly group facilities.

Staff researched RTF bed need methodologies in other CON states. Both Mississippi and Kentucky have need methodologies that generate similar results to the old South

Carolina methodology. We were unable to find a methodology that projects a need comparable to the current number of existing beds in South Carolina.

Therefore, staff is recommending that the Plan re-institute the old need standard of 41.1 beds per 1,000 population age six-21, calculated by Inventory Region. This will show an excess of RTF beds statewide, with no need shown in any region. However, staff also recommends keeping the existing CON standards from the Draft (VII-2-3), because they are more explicit than the previous Plan's standards. As a result of the number of revisions, a copy of the proposed re-written RTF section of the Plan is attached as a separate document.

PROPOSED RE-WRITTEN
CHAPTER VII

RESIDENTIAL TREATMENT FACILITIES FOR CHILDREN & ADOLESCENTS

A Residential Treatment Facility for Children and Adolescents is operated for the assessment, diagnosis, treatment, and care of children and adolescents in need of mental health treatment. This means a child or adolescent up to age 21 who manifests a substantial disorder of cognitive or emotional process, which lessens or impairs to a marked degree that child's capacity either to develop or to exercise age-appropriate or age-adequate behavior. The behavior includes, but is not limited to, marked disorders of mood or thought processes, severe difficulties with self-control and judgment, including behavior dangerous to self or others, and serious disturbances in the ability to care for and relate to others.

These facilities provide medium to long-term care (6 months or longer). Treatment modalities are both medical and behavioral in nature. Some facilities contract with the Continuum of Care for Emotionally Disturbed Children to provide these services. The following facilities are currently licensed or approved as Residential Treatment Facilities:

Region	Facility	County	Beds	FY 2009 Occ. Rate
I	Excalibur Youth Services	Greenville	60	48.1% *1*
I	Generations – Bridges	Greenville	(10)	--- *2*
I	Generations – Horizons	Greenville	(20)	--- *2*
I	Marshall Pickens	Greenville	22	89.0%
I	Springbrook Behavioral	Greenville	68	80.0%
I	Avalonia Group Homes	Pickens	55	55.8% *3*
II	Three Rivers Behavioral	Lexington	20	89.0%
II	Three Rivers – Midlands	Lexington	59	94.0%
II	Carolina Children's Home	Richland	20 (30)	47.3% *4*
II	Directions (DMH)	Richland	37	52.2%
II	New Hope Carolinas	York	150	83.9% *5*
II	York Place Episcopal	York	40	72.3%
III	Palmetto Pee Dee	Florence	59	95.1%
III	Lighthouse of Conway	Horry	30	85.4% *6*
III	Willowglen Academy	Williamsburg	40 (54)	43.0% *7*
IV	Palmetto Low Country	Charleston	32	94.7%
IV	Riverside at Windwood	Charleston	12	--- *8*
IV	Palmetto Pines Behavioral	Dorchester	60	92.0%
IV	Pinelands RTC	Dorchester	14 (28)	--- *9*
	Total (Does Not Include Directions)		741 (809)	80.0%

1 Licensed for 42 beds 12/31/08. CON issued 3/26/09 to add 18 beds for a total of 60, SC-09-15; licensed for 60 beds 6/26/09.
2 Exempted to convert from a Group Home to an RTF.
3 Licensed 9/18/08.
4 Licensed for 20 RTF beds 6/16/09; intend to license 30 total beds.
5 Licensed 11/20/08.
6 Number of licensed RTF beds increased from 16 to 30 10/29/09.
7 Licensed for 40 beds 3/20/09; intend to license 28 total beds.
8 Licensed 3/18/10.
9 Licensed for 14 beds 7/21/10; intend to license 28 total beds.

Services available at a minimum should include the following:

1. 24-hour, awake supervision in a secure facility;

2. Individual treatment plans to assess the problems and determine specific patient goals;

3. Psychiatric consultation and professional psychological services for treatment supervision and consultation;

4. Nursing services, as required;

5. Regularly scheduled individual, group, and/or family counseling in keeping with the needs of each client;

6. Recreational facilities with an organized youth development program;

7. A special education program with a minimum program defined by the South Carolina Department of Education; and

8. Discharge planning including a final assessment of the patient's condition and an aftercare plan indicating any referrals to follow-up treatment and self-help groups.

Each facility shall have a written plan for cooperation with other public and private organizations, such as schools, social service agencies, etc., to ensure that each child under its care will receive comprehensive treatment. In addition, each facility shall have a written transfer agreement with one or more hospitals for the transfer of emergency cases when such hospitalization becomes necessary.

A proposal for Residential Treatment Facilities for Children and Adolescents should have letters of support from the Continuum of Care for Emotionally Disturbed Children, the SC Department of Social Services and the SC Department of Mental Health. Priority consideration will be given to those facilities that propose to serve highly aggressive and sexual offending youths and those with other needs as determined by these State

agencies. In addition, smaller facilities may be given greater consideration than large facilities based on recommendations from the above agencies.

Certificate of Need Standards

1. Except in the case of high management group homes that received exemption from CON through Health and Human Services Budget Proviso 8.35, the establishment or expansion of an RTF requires a CON.

2. The applicant must document the need for the expansion of or the addition of an RTF based on the most current utilization data available. The existing resources must be considered and documentation presented as to why these resources are not adequate to meet the needs of the community.

3. For a new facility, the applicant must document where the potential patients for the facility will come from and where they are currently being served, to include the expected shift in patient volume from existing providers. For the expansion of an existing facility, the applicant must provide patient origin information on the current facility.

4. The applicant must document the potential impact that the proposed new RTF or expansion will have upon the existing service providers and referral patterns.

5. The applicant must provide a written commitment that the facility will provide services for indigent and charity patients at a percentage that is comparable to other health care facilities in the service area.

6. The applicant agrees to provide utilization data on the operation of the facility to the Department.

The bed need methodology to be used in South Carolina is based upon a standard of 41.4 beds per 100,000 children. Since few, if any, children under 6 years of age would be candidates for this type of care, the bed need will be based on the population age 6-21. The projected bed needs by service area are as follows:

Inventory Region I (Anderson, Cherokee, Greenville, Oconee, Pickens, Spartanburg, Union).

Facilities:	Avalonia Group Homes	55 beds
	Excalibur Youth Services	60
	Generations – Bridges	10
	Generations – Horizons	20
	Marshall Pickens	22
	Springbrook Behavioral	68
	Total	235 beds

2016 Population Age 6-21:	267,200
41.4 Beds/100,000 Population:	x .000414
	110 beds
	- 235 beds
Need Shown:	(115) beds

Inventory Region II Abbeville, Chester, Edgefield, Fairfield, Greenwood, Kershaw, Lancaster, Laurens, Lexington, McCormick, Newberry, Richland, Saluda, York.

Facilities:		
	Carolina Children's Home	30 beds
	New Hope Carolinas	150
	Three Rivers Behavioral	20
	Three Rivers – Midlands	59
	York Place	40
	Total	299 beds

2016 Population Age 6-21:	287,150
41.4 Beds/100,000 Population:	x .000414
	119 beds
	- 299 beds
Need Shown:	(180) beds

Inventory Region III Chesterfield, Clarendon, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter, Williamsburg.

Facilities:		
	Lighthouse of Conway	30 beds
	Palmetto Pee Dee	59
	Willowglen Academy	54
	Total	143 beds

2016 Population Age 6-21:	176,440
41.4 Beds/100,000 Population:	x .000414
	119 beds
	- 143 beds
Need Shown:	(24) beds

Inventory Region IV Aiken, Allendale, Bamberg, Barnwell, Beaufort, Berkeley, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper, Orangeburg.

Facilities:		
	Palmetto Low Country	32 beds
	Palmetto Pines Behavioral	60
	Pinelands RTC	28
	Riverside at Windwood	12
	Total	132 beds

2016 Population Age 6-21:		247,360
41.4 Beds/100,000 Population:		x .000414
		103 beds
		- 132 beds
	Need Shown:	(29) beds

The Directions program primarily serves court-ordered patients from the Department of Juvenile Justice (DJJ). As a statewide facility serving a restricted population, it is not included in the regional inventories for bed need calculations.

Relative Importance of Project Review Criteria

The following project review criteria are considered to be the most important in evaluating certificate of need applications for this service:

a. Compliance with the Need Outlined in this Section of the Plan;
b. Distribution (Accessibility);
c. Projected Revenues;
d. Projected Expenses;
e. Record of the Applicant;
f. Ability of the Applicant to Complete the Project;
g. Cost Containment; and
h. Staff Resources.

Residential treatment facility beds for children and adolescents are distributed statewide and are located within sixty (60) minutes travel time for the majority of residents of the State. The benefits of improved accessibility will be equally weighed with the adverse effects of duplication in evaluating Certificate of Need applications for this service.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

13. CARDIAC CATHETERIZATION

STAFF NOTICE: The utilization figures in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the Draft Plan submitted to the SHPC. As a result, the projected need could be different from that shown in the Draft Plan.

COMMENT: Spartanburg Regional Healthcare (page 80) commented that "radioactive dye" be replaced by "contrast material" in the definition of cardiac catheterization on page VIII-1. They also suggested replacing the word "intracardiac" with "cardiac" in the first sentence of the final paragraph of VIII-1.

STAFF RESPONSE: Staff recommends accepting these changes.

COMMENT: The SCHA (page 189) and Spartanburg Regional Healthcare (page 422) noted that ICD-9-CM code 36.06 (Insertion of Coronary Stents) was omitted from the list of therapeutic cardiac catheterization procedure codes on page VIII-4. However, the code does accurately appear on page VIII-5 in the discussion of calculating diagnostic equivalents.

STAFF RESPONSE: The code was accidentally deleted and has been added back.

COMMENT: Mary Black Health System (pages 209-355) requested that standards allowing elective PCI without open heart back up be created in the Plan. Recent studies show comparable outcomes between elective PCI sites without surgical back up and hospitals with open heart surgery programs (pages 209-211). The guideline-writing groups in other countries have revised their recommendations to allow elective PCI without back up (page 211). Many states also allow it (pages 211-212, 213). Allowing elective PCI without back up will increase the overall quality of cardiac cath programs (page 212). It will also increase access to elective PCIs (page 212). Copies of a number of studies supporting this position were attached, including Dehmer (pages 215-218), Frutkin (pages 219-223), Ting (pages 224-234), Sing (pages 235-242), and Kutcher (pages 243-253), among others. CON standards were also included from West Virginia (pages 260-281), New York (pages 282-293), Kentucky (pages 294-302), and Tennessee (pages 303-327).

Mary Black Health System also submitted proposed revisions to the Draft Plan, which are summarized on pages 213-214. The proposed re-written Cardiovascular Care section can be found in its entirety on pages 336-355. The proposed revisions include:

If the institution performs both emergency and elective PCI, the institution should perform a minimum of 150 PCI procedures, including a minimum of 36 emergency PCI procedures, per year by the second year of the program's operation.

Any institution performing elective PCI must adopt patient selection and transfer guidelines specific to elective PCI procedures.

Institutions performing PCI must have highly skilled interventional cardiologists on staff. These cardiologists must have performed an adequate number of PCI procedures per year to maintain clinical proficiency.

All support personnel must be trained in the management of PCI patients.

Institutions performing elective PCI without onsite open heart surgery capabilities must establish a close alliance with off site open heart surgery programs, including formalized and tested protocols for emergency transfer of patients.

The institution must activate emergency transportation at the first clear signs of a PCI complication, thereby ensuring that the time to the initiation of cardiopulmonary bypass does not exceed 120 minutes.

Appropriate outcomes data must be collected by the institution and submitted for comparison with state or national performance standards.

COMMENT: Georgetown Hospital System (pages 21-23) requested that the SHPC reconsider its position on elective PCI. They stated that the risk of complications requiring emergency surgery has decreased to a low enough number to indicate it can be performed in hospitals without back-up (page 21). A National Cardiovascular Data Registry (NCDR) review found comparable risk-adjusted mortality rates between off site PCI centers and PCI centers with cardiac surgery on site (page 22). There are currently 10 states participating in the C-PORT II study (page 22). A number of CON states have provisions allowing elective PCI without on site open heart surgery (pages 22-23). Reduced travel time increasing convenience for family members and continuous involvement of local physicians are also cited as supporting this shift (page 23).

COMMENT: A joint position paper was submitted by Grand Strand Regional Medical Center, Providence Hospitals, Self Regional Healthcare and Spartanburg Regional Hospital (pages 6-19) in opposition to allowing elective PCI without open heart back-up. The major arguments presented were: elective PCI without back up is not endorsed by the current American College of Cardiology/American Heart Association (ACC/AHA) guidelines (pages 8-9, 11); patients undergoing PCI in hospitals without cardiac surgery are more likely to die (pages 9,11); the distribution of open heart providers is adequate to serve the state (pages 9-10, 16); and most of the states that allow elective PCI without back up are participating in demonstration/pilot projects such as the C-PORT II trials (pages 10, 14-16).

The position paper also noted that some of the comments submitted on this issue during the public comment period confused the concepts of emergency PCI versus elective PCI (pages 12-14). It also offered criticism at several of the proposed standards in the initial proposal that was submitted to the SHPC to allow elective PCI without back up (pages 17-19).

COMMENT: Palmetto Health (page 469) opposes the proposal to allow elective PCI without open heart back-up because it is not endorsed by the current ACC/AHA guidelines, and because the current distribution of open heart surgery providers is adequate to serve the state.

COMMENT: We received a number of letters from physicians in opposition to the proposal to allow elective PCI without open heart back-up. Carolina Cardiology Associates of Greenville (pages 62-63) submitted letters from 26 physicians from their group in opposition. Upstate Cardiology (pages 454-455), also from Greenville, submitted 11 letters of opposition from their practice. They cited two major reasons for opposing the proposal. First, the ACC/AHA guidelines do not support it. Second, given the number of existing open heart providers in the state, there is no access issue that would justify putting patients at higher risk by performing elective PCIs at hospitals without open heart back up.

COMMENT: The SCHA (pages 189-190) supports the Planning Committee's decision to not remove the requirement for open heart back-up for elective PCIs. However, they recommend revisiting the issue during the next Plan development process, because they anticipate technological advances and new evidence-based research from other states for the SHPC to consider.

STAFF RESPONSE: The current Standard 8 in the Draft Plan (VIII-7-9), which allows emergent PCI without open heart back up, is based on the ACC/AHA/SCAI guidelines. The Department relied on the expert opinion of these organizations that these procedures could be safely performed under certain guidelines when the standard was incorporated into the Plan. The C-PORT II study, among others, is intended to determine whether these procedures can also be performed on an elective basis without back up. However, at this time, the ACC/AHA/SCAI guidelines have not been amended. Therefore, staff recommends that no change be made to the standards at this time. It is anticipated that the guidelines may be revised as additional evidence is gathered, so it would be appropriate to re-visit the issue during the next planning process.

COMMENT: AnMed Health (page 153) noted that the footnotes for the cardiac cath inventory (VIII-13) were omitted from the Draft.

STAFF RESPONSE: Staff set the wrong print range for the Draft; this has been corrected.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

14. OPEN HEART SURGERY

STAFF NOTICE: The utilization figures in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the Draft Plan submitted to the SHPC. As a result, the projected need could be different from that shown in the Draft Plan.

COMMENT: Georgetown Hospital System (page 23) and the SCHA (page 190) supported removing the seven to one ratio of diagnostic caths to open heart surgeries standard from the Draft Plan. Roper St. Francis Healthcare (page 66) stated that they felt the ratio was a useful tool but understood the Committee's rationale in removing the standard.

COMMENT: Grand Strand Regional Medical Center (pages 461-463) requested that the SHPC reinstate the seven to one ratio standard into the Plan. The ratio was used to ensure that an applicant for a new open heart surgery program would be able to forecast it will perform at least 200 adult cases within three years of initiation of services. Volume is critical to ensure that providers operate at high quality and efficiency levels. The initial standard of four to one was revised in the 2008-2009 Plan to seven to one based on the growth in PTCA and decline in open heart cases. The actual ratios have been slightly above seven to one for 2006-2008.

STAFF RESPONSE: The previous standard of a four to one ratio was revised during the 2008-2009 Plan development process based on more current data. At that time, staff also recommended re-looking at the issue during the development of the current Draft. The staff recommendation in the synopsis sent to the SHPC was to delete the standard. We found no other state that uses such a methodology and when we applied this standard to the utilization data from other states we found no consistency in the results. Even just looking at the South Carolina open heart surgery providers, the 2008 data varied between 2.20:1 and 11.41:1. Staff does not recommend re-instating this standard due to its lack of predictability.

COMMENT: Grand Strand Regional Medical Center (pages 463-464) proposed a revision to Standard 6 (VIII-18). The existing standard states that no new programs can be approved if they cause the caseload of existing programs within the proposed service area to drop below 350 adult cases per year. Since the 350 figure is an important quality and efficiency issue, then the impact of new open heart surgery providers should be considered on all existing programs, regardless of whether they are inside or outside a defined service area. Grand Strand proposed the following amendment to Standard 6:

6. No new open heart surgery programs shall be approved if the new program will cause the annual caseload of other **existing open heart surgery** programs ~~within the proposed service area~~ to drop below 350 adult procedures or 130 pediatric procedures per open heart surgery unit.

STAFF RESPONSE: There has been a similarly worded version of this standard in every Plan since at least the 1998 Plan. In all those Plans, "service area" has been used in the standard. The service area for an open heart surgery program is defined in the current Draft [Standard 5A (VIII-17)] as all facilities within 60 minutes one-way automobile travel time. It appears counter-intuitive to have a service area defined in one standard and have a subsequent standard that measures impact statewide rather than within the proposed service area. Taken at its most extreme, this would be saying you couldn't approve an open heart program at AnMed because it might drive MUSC below 350 cases [note: AnMed already has open heart surgery]. At the same time, staff recognizes that programs that are further than 60 minutes apart can impact one-another (ex. McLeod and Carolinas in Florence are approximately 80 miles from Grand Strand in Myrtle Beach but presumably compete for the patients living between the facilities). This is a difficult issue and it might be appropriate to re-look at the service area definitions. However, staff does not believe it would be appropriate to make such a change to the existing standard without the input of the other open heart surgery hospitals in the state. Therefore, staff recommends making no changes at this time, and instead address the service area and volume impact issues with the provider community during the next planning cycle.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

15. RADIOTHERAPY & RADIOSURGERY

STAFF NOTICE: The utilization figures in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the Draft Plan submitted to the SHPC. As a result, the projected need could be different from that shown in the Draft Plan.

COMMENT: Roper St. Francis Healthcare (page 67) noted that radiotherapy and radiosurgery are being used to treat cancer in other parts of the body in a procedure called Stereotactic Body Radiotherapy (SBRT). This should be added to the definitions.

STAFF RESPONSE: Staff proposes the following additional definition be added to page IX-2 of the Draft:

> Stereotactic body radiation therapy (SBRT) is a precision radiation therapy delivery concept derived from cranial stereotactic radiosurgery. It is characterized by one to five fraction delivery of focal high-dose radiation while limiting dose to surrounding normal tissues. SBRT has become an established treatment technique for lung, liver, and spinal lesions.

COMMENT: Spartanburg Regional Healthcare (page 80) requested that the definition of IGRT on IX-2 be revised. The current definition is vendor-specific. IGRT can be combined with 3DCRT as well as IMRT, and On-Board Imaging (OBI) scans are not required. They suggest the following language:

> Image-Guided Radiation Therapy (IGRT) combines with IMRT or 3DCRT to visualize (by means of EPIDs, kV scans or mV scans) the patients' anatomy during treatments. This allows for confirmation of beam location and adjustments of the beams if needed during treatments due to breathing. IGRT facilitates more accurate patient positioning and reduces healthy tissue damage.

STAFF RESPONSE: Staff proposes the following revision to the definition of IGRT:

> Image-Guided Radiation Therapy (IGRT) combines **with** IMRT **or 3DCRT** ~~with On-Board Imaging (OBI) scans~~ **to** ~~It~~ visualizes **(by means of EPIDs, kV scans or mV scans)** the patient's anatomy during treatments. **This** ~~and~~ allows for **confirmation of beam location and** ~~real-time~~ adjustment of the beams **if needed** ~~Since tumors move between treatments and~~ **during treatments due to breathing.** IGRT **facilitates more accurate** ~~ensures correct~~ patient positioning and reduces healthy tissue damage.

COMMENT: RC Cancer Centers (pages 411-414) suggested an alternative to setting a numerical capacity standard for specific types of technology. Instead, they suggest weighting treatment types for patients at each provider and evaluating capacity in terms of weighted or equivalent treatment volume. The Georgia Megavoltage Radiation Therapy rules categorize types of treatment and assign a weighted value to each type. They provided a sample table showing differing results for three comparable providers (page 413). They recommend amending the JARs to capture utilization data by CPT code (pages 413-414). Accuray (page 473) also provided the values for treatment types from the Georgia Megavoltage Radiation Therapy Rules.

STAFF RESPONSE: This approach was used previously in the 1995 and 1996 Plans, using what were then called Equivalent Standard Treatment Visits (ESTV's). Like the Georgia methodology, visits were classified as Simple, Intermediate and Complex, with additional values added-on for complicated procedures. The JAR was modified to capture these data. However, some facilities were having to manually make these calculations as their data systems were not set up to report the numbers as needed for the Plan and there was great variability in the results received. As a result, the recommendation was made to return to visits as the measure of capacity starting with the 1997 Plan. The concept of returning to an ESTV-like methodology was briefly broached during the 2008-2009 Plan drafting process. With the improvements in data systems it might be easier to collect these data now and this proposal can be discussed during the next planning cycle.

COMMENT: Roper St. Francis Healthcare (page 67) recommended that their Cyberknife should be included in the definition and inventory of radiosurgery rather than radiotherapy devices.

STAFF RESPONSE: This issue was discussed at length during the development of the 2008-2009 Plan. As noted, definitions are used interchangeably and not consistently. The distinction made in the definitions of radiotherapy and radiosurgery in the Plan was that radiosurgery is a single-session procedure whereas radiotherapy is fractioned into several smaller doses. A Gamma Knife performs radiosurgery in one visit, whereas a Cyberknife performs similar treatment in two-five sessions. That is why Cyberknife was designated as a linear accelerator designed strictly to perform stereotactic radiotherapy.

COMMENT: Accuray (pages 473-474) noted that many modern delivery systems perform a combination of IMRT, IGRT, conventional, and in some cases stereotactic treatment regimens. A system primarily dedicated to IMRT will have a lesser capacity than an identical system dedicated to conventional treatments. Accuray suggested that the Department adopt a policy of collecting annual utilization data that delineates both patients and patient visits by the applicable treatment regimen (External Beam, IGRT, IMRT, SRS/SRT).

STAFF RESPONSE: Staff is not opposed to the concept of segmenting the data reported by regimen.. However, since the JAR is intended to be single report for hospitals to fill out for DHEC, Office of Research and Statistics (Budget & Control Board), and the American Hospital Association, any modifications to the JAR would have to be

coordinated between all parties. It would be most relevant to collect this data if we were to utilize a need methodology that differentiated between these treatment regimens.

COMMENT: Accuray (pages 471-472) provided background information on the new Accuray Cyberknife VSI System. Staff had proposed increasing the capacity standards for a Cyberknife from 1,000 treatments to 2,000 treatments per year. Accuray indicated that extensive efforts had been made to reduce treatment times but that doubling capacity was not yet supported by practical experience. It should also be noted that the treatment capacity would be a function of disease incidence and treatment mix, including dosing regimens. Intracranial and spine treatments have a greater potential for reduced treatment times versus lung tumors. They requested that the Plan not show an increase in the capacity standard.

STAFF RESPONSE: Staff notes that the information on decreased treatment times was provided by Accuray themselves. In the January, 2009 issue of "Focus on Radiology," produced and distributed by Accuray, there was a message from Chris A. Raanes, CEO, that stated in part: "...This suite of products works together to significantly shorten the treatment times offered by the Cyberknife system... The treatment time improvements were achieved while making the planning function faster and more intuitive. The net result is that treatment times for many procedures are roughly cut in half at the sites running the latest version of the Cyberknife system." The same publication contained an article entitled "Oklahoma Cyberknife Center Cuts Treatment Time in Half with Next Generation Cyberknife Technology." It states in part: "Using many of the Cyberknife System's latest advancements, Oklahoma Cyberknife LLC, operated in partnership with US Radiology has drastically reduced treatment planning and delivery times. Compared to treatments performed using earlier Cyberknife System models at other US Radiology centers, Oklahoma Cyberknife has noted an overall reduction in treatment times of 50 percent on average. 'The next generation Cyberknife System incorporates a number of new features that enhance treatment planning and result in faster treatment times' said Diane Heaton, MD, medical director at Oklahoma Cyberknife... 'With these advanced tools, I believe we will progress to the point of doing 10-15 Cyberknife treatments a day.' ... 'Even after just two months, it is clear that the improvements made to the Cyberknife System will enable us to increase the number of patients we expect to treat at our Oklahoma facility,' said Greg Spurlock, chief operating officer of US Radiology. 'The next generation Cyberknife System is making such a significant, positive impact on our business model and efficacy of our Oklahoma facility that we are considering upgrading the Cyberknife Systems at other centers in order to better meet demand.'

Staff initially proposed increasing the capacity for new Cyberknife Systems to 2,000 treatments per year while keeping the capacity for the existing Cyberknife at Roper Hospital at 1,000 treatments per year. Staff relied on Accuray's own statements that the newest model of Cyberknife would be more efficient with faster treatment times. Implicit in the equation is the fact that if treatment times are approximately cut in half, then there should be the potential to increase the number of patients treated per day [note Dr. Heaton's projected daily use above would equate to 2,500 – 3,750 treatments/year]. Even in Accuray's comments on the Draft (page 475) they indicated that the VSI model offers

the opportunity to treat more patients. In addition, Roper St. Francis Hospital recommended a capacity of 2,000 treatments for the Cyberknife VSI (page 67).

COMMENT: Spartanburg Regional Healthcare (page 81) and the SCHA (page 190) recommended the following capacity standards:

Conventional linear accelerator:	7,000
Linac with IMRT/IGRT:	5,000
IMRT/IGRT with stereotactic:	4,500
"New Model" Cyberknife	2,000
"Current Model" Cyberknife	1,000

COMMENT: Roper St. Francis Healthcare (page 67) recommended similar standards to those proposed by Spartanburg Regional (page 81) et. al., with the distinction that both models of Cyberknife be considered as Radiosurgery equipment, along with the Gamma Knife (capacity of 300), rather than as Radiotherapy equipment.

COMMENT: Georgetown Hospital System (pages 23-24) and MUSC (pages 419-420) requested that the capacity for IMRT and IGRT systems be set at 5,500 treatments per year per unit, based on 22 patients per day, five days per week, for 50 weeks per year.

STAFF RESPONSE: After reviewing all the comments on this issue, staff recommends accepting the capacity standards proposed by Spartanburg Regional Healthcare and the SCHA:

Conventional linear accelerator:	7,000
Linac with IMRT/IGRT:	5,000
IMRT/IGRT with stereotactic:	4,500
"New Model" Cyberknife	2,000
"Current Model" Cyberknife	1,000

The need projections will be adjusted accordingly.

COMMENT: SCHA (190) supports the provision allowing existing provider to document a specialize use of the equipment and to propose an annual capacity based upon that use and to project a need for additional equipment based on this specialized use.

STAFF RESPONSE: Accepted as information.

STAFF RECOMMENDATION: The Draft Plan has no Quality standards listed for Radiotherapy and Radiosurgery. Since the Draft was published, a new initiative was announced by the Medical Imaging & Technology Alliance and the Advanced Medical Technology Alliance to incorporate safety-check mechanisms into radiation therapy equipment. Staff recommends the addition of the follow statement on Quality:

Incorrect doses of radiation can be dangerous. Two patients in New York died from lethal overdoses. In response, the Medical Imaging & Technology Alliance and the Advanced Medical Technology Alliance recently announced the Radiation Therapy Readiness Check Initiative, which is intended to incorporate safety-check mechanisms into radiation therapy equipment. The manufacturers have agreed to make equipment modifications to improve patient safety, by preventing equipment from operating unless the users verify that safeguards are in place.

The initiative requires medical physicists to record the performance of quality-assurance reviews of treatment plans. Technicians are required to perform beam modification checks, verify correct placement of machine accessories, and confirm correct patient placement. Individual manufacturers will be responsible for incorporating the safety-check software into new equipment and creating software add-ons that can be incorporated into existing equipment. However, some older machines may not be capable of adding the safeguards.

COMMENT: Platt HMC (page 452) questioned whether a CON had been issued for Lancaster Radiation Therapy because the footnote indicated that the appeal had been settled but didn't indicate a CON number for the project.

STAFF RESPONSE: This was corrected in the revised version of the Radiotherapy section of the Draft (IX-10).

COMMENT: Dr. Ken Vanek (page 457) noted that there is another cranial-based SRS system that is currently not approved by the FDA but is in use in other countries. When it is approved it should be considered in the same category as a Gamma Knife and the name of the section should be changed to something like "Cobalt 60 Cranial SRS."

STAFF RESPONSE: Accepted as information.

COMMENT: Trident Health System (pages 87-147), Colleton Medical Center (pages 200-201), and Grand Strand Regional Medical Center (pages 465-466) objected to a "new" Standard 9 in the Stereotactic Radiotherapy (Gamma Knife) section (IX-5). This standard states the applicant should document how it intends to provide accessibility for graduate medical education students because of the unique nature and limited need for this equipment. Such a proposal would prevent any provider that does not have support from an academic institution from successfully applying for a CON and would set a dangerous precedent. Trident also submitted copies of the current ACGME Program Requirements for Graduate Medical Education in Neurological Surgery and Radiation Oncology and the ACGME Institutional General Requirements (pages 89-147).

STAFF RESPONSE: This standard already appears in the current 2008-2009 Plan [Standard 9 on II-70]. In fact, Andrea Brisbin (Parker Poe) provided comments on behalf of Trident Health System during the public comment period during the 2008-2009 Plan

development process, with the letter carbon copied to Mr. Gunn, so it is unclear why it is being viewed as a "new" proposal.

The staff response on the comments during the 2008-2009 Plan development was:

> Staff concurs that it would be desirable for neurosurgery and oncology residents to have access to the technology and experience needed for successful completion of their training programs. However, staff has concerns with stating a "preference" for a particular hospital in a potentially competitive review process. Staff recommends that any applicant be required to state how they would facilitate access to this technology by graduate medical education programs:
>
> > Because of the unique nature and limited need for this type of equipment, the applicant should document how they intend to provide accessibility for graduate medical education students in such fields as neurosurgery and oncology.

Staff does not recommend any change to this standard.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

16. PET & PET/CT

STAFF NOTICE: The utilization figures in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the Draft Plan submitted to the SHPC. As a result, the projected need could be different from that shown in the Draft Plan.

COMMENT: Roper St. Francis Healthcare (page 66) supported incorporating the new standard that requires applicants to seek accreditation by January 1, 2012.

STAFF RESPONSE: None required.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

17. AMBULATORY SURGICAL FACILITIES

COMMENT: Parker Poe (pages 47-48) requested confirmation as to which proposed revisions the SHPC adopted into the Draft Plan at the meeting.

STAFF RESPONSE: The staff reply is included on page 47.

COMMENT: Lynn Bailey (pages 28-29) commented on the evolving physician practice model changes. Greenville Hospital System is anticipated to employ more than half of all physicians practicing in the county, in some specialties controlling all providers. Her concern is the potential conflict of interest because of the influence the hospitals have on the business and economic side of physician practices. In particular, Standard 3 [**sic**] on page XI-2 requires an applicant to submit detailed letters from referring physicians citing the number of referrals they will make or the reasons the existing providers are inadequate [**Staff note**: this is actually Standard 5]. Hospital-employed physicians are free to refer patients to any appropriate clinical provider, but they may be restricted from writing the required letters documenting those referrals if the employer owns a competing service. Because of this inherent conflict of interest, the standard requiring letters of support and the number of referrals should be removed. Applicants should be able to substantiate a reasonable level of utilization with other data sources and general letters of support.

STAFF RESPONSE: The current language in Standard 5 was created when new criteria were added to the 2004-5 Plan in lieu of a moratorium on new ASF applications. The standard requires physicians other than those affiliated with the proposed project to state how many patients they intend to refer to the applicant or why they believe the existing providers are not meeting the needs of the community. This gives us a basis to evaluate the accuracy of their utilization projections and sources of referrals in their CON applications.

It is difficult to measure what impact hospitals purchasing physician practices has had on ASFs because we have had relatively few CON applications in the past few years. At this time, almost every county in the state is open to applications for both general and endoscopy-only ASFs. While it can be argued that it may now be harder to obtain physician letters of support, staff does not recommend deleting this standard. Physician letters are more meaningful to the Department than reams of signed petitions from the general public.

COMMENT: Doug Bryant (page 51) offered a proposed definition of an "Endoscopy Center."

STAFF RESPONSE: The definition of "Endoscopy ASF" that appears in the Draft (XI-1) was developed by staff in conjunction with Dr. Coleman Buckhouse.

COMMENT: Bon Secours St. Francis Health System (pages 357-358) disagreed with the revised definitions of an "Endoscope" and "Endoscopy ASF" as they appear in the Draft (XI-1). These definitions do not reflect the spirit in which endoscopy was originally separated from general ambulatory surgery. The original intent was to segregate the gastroenterology endoscopy needs and this new definition appears to include a broader definition than was originally intended. The definition of "Endoscopy-only" ASFs should remain focused on gastroenterology-related procedures.

COMMENT: Bon Secours St. Francis Health System (page 358) recommended that Standard 10 (XI-3) be amended to remove the following phrase, as there is no basis to differentiate based on this population threshold or for specialization:

> The requirements that all ASFs with endoscopy suites must have been licensed and operational for an entire year and submitted utilization data to the Department will not be applied to applicants for a new endoscopy-only ASF filing in a county having a current population of greater than 100,000 people.

COMMENT: Roper St. Francis Healthcare (page 66) and MUSC (pages 418-419) also supported removing the above phrase from Standard 10. This new exemption is not consistent with the classification and handling of endoscopy operating rooms in prior Plans and establishes a precedent of segmenting CON standards based on population and type of operating room. Unless the Plan projects a need for new surgical facilities in each county, it must retain the requirements that in no case can more than one new ASF be approved in a county and that all existing ASFs have been licensed and operational for a year and submitted data to DHEC before a new application can be filed. It is even more important to control proliferation and prevent unnecessary duplication of health care facilities and services in counties with larger populations. To remove DHEC's ability to adequately gauge utilization prior to the approval of additional facilities is inconsistent with the purpose of health planning and the Regulation.

COMMENT: Spartanburg Regional Healthcare (page 81) and the SCHA (page 191) do not support the revised version of Standard 10. It is inconsistent with endoscopy suites in previous Plans and establishes a precedent for segmenting CON standards based on the population of counties and for those facilities that are endoscopy only. They recommend removing Standard 10 in its entirety and be replaced with Standards 8, 9, and 10 from page II-77 of the current 2008-2009 Plan.

STAFF RESPONSE: There were no comments received in favor of revising the definition of endoscopy and the related need standards in the Draft. There were multiple responses in opposition to the proposed revisions, although all of the respondents were hospitals. It would have been useful to receive feedback from ASFs but no comments were submitted [**Staff note**: Roper does operate 3 ASFs]. Based on the lack of support, it appears questionable as to whether these standards should be amended.

COMMENT: Spartanburg Regional Healthcare (page 81) noted that the first sentence in the final paragraph on XI-3 implies that but does not specifically identify CMS as an accrediting organization. They propose the following alternative wording:

> Facilities providing ambulatory surgery services must conform to local, state, and federal regulatory requirements and must commit to seek accreditation from CMS or any regulatory agency with deemed status.

STAFF RESPONSE: Staff agrees with the gist of the recommendation but notes that organizations with deemed status are not regulatory agencies. They are accrediting bodies. Staff recommends the following revision:

> Facilities providing ambulatory surgery services must conform to local, state, and federal regulatory requirements and must commit to seek accreditation from **CMS or any accrediting body with deemed status** ~~nationally recognized organization, such as The Joint Commission (TJC), the Accreditation Association for Ambulatory Health Care (AAAHC), or the American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF)~~. Ambulatory surgical services are generally available within 30 minutes one-way automobile travel time of most South Carolina residents. Most ASFs operate five days a week, with elective surgery being scheduled several days in advance.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

18. FREESTANDING EMERGENCY SERVICES

COMMENT: Roper St. Francis Healthcare (page 66) commented that the Roper Hospital Diagnostics & ER – Berkeley County was not included in the list of Freestanding Emergency Services on page XI-11 of the Draft Plan.

STAFF RESPONSE: Staff will add this facility to the inventory.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

19. NURSING FACILITIES

STAFF NOTICE: The need calculations in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the need calculations for submission to the SHPC. This would also mean changing the years used in the population projections. As a result, the projected need for beds or a particular service could be different from that shown in the Draft Plan.

COMMENT: Spartanburg Regional Healthcare (pages 82-83) noted that the Draft Plan shows a need for 6,708 additional beds. Because of the lack of Medicaid funding, few additional beds have been built, making it difficult for hospital case managers to discharge patients to more appropriate levels of care. This problem must be addressed in order for patients to receive timely and appropriate care.

STAFF RESPONSE: Staff concurs that the lack of Medicaid funding limits the creation of new facilities. The Medicaid Patient Days Permit Program, which staff partially administers, controls Medicaid utilization. DHEC cannot issue a CON for a Medicaid-participating nursing facility, because we cannot guarantee there will be funding available for the beds. Therefore, applicants can only apply for Medicare and private pay beds. Medicaid used to pay for 72-74% of all patient days in the state. It is now down to ~66%, but it is still difficult to operate a facility without Medicaid. Without an infusion of additional Medicaid funding, which appears unlikely given the current budget situation, we can only foresee the bed need increasing as the population ages.

A related issue is the age of facilities. We have a number of older nursing facilities in this state that will eventually require upgrades/repairs or replacement. The tight financial market could make it more difficult for providers to secure funding for these projects.

STAFF RECOMMENDATION: Institutional Nursing Facility beds (XII-8) are restricted to residents of a retirement community. Since these beds are not accessible to the general public, these beds are inventoried separately and not counted in the bed need calculations for nursing homes. However, since these beds are restricted, they are not eligible to participate in either Medicare or Medicaid. A distinction should be made on the facility's license that these beds are classified as INF beds.

We have 16 retirement communities in the state that have a combination of general and institutional beds. Some of their beds are available to the general public while others are restricted to residents of the retirement community. Only the beds that are available to the general public should be certified to serve Medicaid and/or Medicare patients.

DHEC staff has recently become aware that several retirement communities have INF beds that have been certified for Medicaid and/or Medicare. In some cases this certification was done a number of years ago. It is not known exactly how many of these INF beds are currently filled by a Medicare or Medicaid patient.

We are developing a solution. It appears the facilities will have to either convert them to beds accessible to the general public or de-certify those beds and keep them as INF. We have already had one facility that filed a CON to convert their INF beds to general beds, and another facility has opted to de-certify their INF beds.

Converting these INF beds to general beds would be contingent upon the projected need for nursing home beds in those counties. However, we have identified one facility where the projected number of general beds needed in the county is less than the number of Medicaid and Medicare patients currently residing in INF beds. Obtaining the number of beds available in the Plan would not fully address the problem.

It is a Catch-22 situation. The current situation can't continue, but at the same time, it would create a hardship for the existing patients in those beds, and their families, to make them re-locate to another certified home.

Therefore, staff is proposing that a new Standard 3 be added on XII-1, allowing the flexibility to exceed the projected bed need in order to re-classify these beds as community beds. Given the unique nature of this situation it should not create a precedence of "special request" Plan amendments. It should also not unduly impact other providers in the county.

STAFF RESPONSES TO COMMENTS ON THE DRAFT PLAN

20. HOME HEALTH AGENCIES

STAFF NOTICE: The utilization figures in the Draft Plan were based on the 2008 Joint Annual Reports (JARs) data. We have received almost all of the 2009 JARs and are currently entering the data from them. If we are able to reconcile all of the potential data questions quickly, we intend to incorporate the more current numbers into the Draft Plan submitted to the SHPC. As a result, the projected need could be different from that shown in the Draft Plan.

COMMENT: The South Carolina Home Care & Hospice Association (page 366) noted that they support a strong CON program and believe that this has prevented our state from having an over-abundance of HHAs, such as in Texas and Florida.

STAFF RESPONSE: Accepted as information.

COMMENT: Rest Assured (pages 73-75) asked a number of questions that staff will summarize the major points for brevity and respond to them: 1) is there consideration to requiring CON for hospice; 2) since the costs for HHA are minimal, why aren't they exempt from CON; 3) the population data does not concur with the Budget & Control Board's estimates; 4) isn't it a conflict of interest for DHEC to review CONs and also provide home health in most counties; 5) the Plan is using projections and estimations rather than factual data; 6) there has been a significant increase in Richland County HHA utilization so why is there not a need for another HHA; 7) the Plan doesn't show how many patients are served by each agency in a county.

STAFF RESPONSE: The following responses are provided:

1) This is an issue that has come up and may be raised by the General Assembly in the next session. Staff has not taken a position on any such proposal but anticipates studying the concept this fall to assist in determining what the Department's position would be should such a bill be introduced.

2) CON for HHAs is required by the Licensing regulations. The only exemptions are for HHAs that are restricted to serving residents of a retirement community. There are 13 such agencies statewide.

3) The population projections in the Draft came from the State Demographer's office (ORS), which is part of the Budget & Control Board. They are the official population estimates provided by that office for us.

4) This issue was discussed back in the 1980s when we started reviewing HHAs under CON. Staff was not present then so is unaware of what determinations were made.

5) This comment is unclear, since the need methodology uses "factual" data (2008 actual utilization) in calculating the projected future utilization used to determine need.

6) A need methodology determines whether the existing providers, based on lower-than-expected utilization, potentially underserve a county. It looks for unmet need. If the utilization in a county exceeds the projected number of patients, then it presumes the needs are being met by the existing agencies.

7) The Plan used to report HHA utilization both by agency and county. However, as a result, the HHA section was by far the largest section of the Plan. For example, in the 2001 Plan, the HHA section was 27 pages long; whereas the hospital bed need section was 15 pages. The decision was made to only report utilization by agency in the Plan.

COMMENT: The SC Home Care & Hospice Association (page 366) would support the future inclusion of both home care hospice and inpatient hospice under the CON process.

STAFF RESPONSE: Inpatient hospice services are currently reviewed under CON and there are standards in the Draft (XII-9-11). Legislative approval would be required to put home care hospice under CON.

COMMENT: The SC Home Care & Hospice Association (page 367) recommends that home-based hospice utilization should be factored into the need calculations.

COMMENT: CarePro Health Services (pages 1A-2) expressed concern that the proposed methodology did not include utilization from hospice agencies, Community Long Term Care (CLTC) providers and local Agencies on Aging.

STAFF RESPONSE: As previously noted, hospice services are not reviewed under CON. Therefore, utilization data are not collected from these facilities. Likewise, CLTC agencies and other in home providers do not provide data to the Department. Staff recognizes that there is a vast array of home care services in the state. For completeness this list would also need to include private duty nurses. However, it is not clear how CarePro proposes that the Department somehow amalgamate all these different providers into a need for home health agency services.

COMMENT: CarePro Health Services (page 2) states that existing agencies routinely avoid or decline to serve patients in rural areas or certain urban neighborhoods. In some counties they only serve the bare minimum number of patients and only focus on certain zip codes. They want the Department to amend the JAR to require agencies to report the number of patients referred versus served by zip codes.

STAFF RESPONSE: The allegation that existing HHAs are routinely refusing to serve rural patients would appear to be an issue to bring up with DHEC Health Licensing. Regulation 61-77 requires HHAs to serve an entire county, so if there is evidence that

agencies are not complying with the regulations it should be shared with the appropriate agency staff. Ms. Aiken, the person making this statement, is President-Elect of the South Carolina Home Care & Hospice Association, so she appears to be faulting her fellow members for not complying with the regulations.

However, the proposal to collect JARS data by zip code, and then to search for variations in care, is totally unrealistic in the amount of data that would have to be reported and the workload that would be required to analyze it. There are 27 residential zip codes for Richland County and 14 for Lexington County alone. With eight HHAs licensed for Richland County and seven for Lexington County, staff would be looking at 314 individual zip code analyses just for these two counties. Some HHAs are licensed for four or more counties, so the JAR would have to be jerry rigged for additional reporting room for all this additional information. Carried to its most extreme, this would require Alere-Piedmont to report their utilization in 33 counties by zip code.

It is not clear how an agency could be compelled to report "referrals" since this is not a data element used in the need methodology. The difference between the number of referrals and the number of patients actually treated is meaningless without a reporting mechanism on why the visits did not occur (ex. "unable to contact patient").

By themselves the actual numbers by zip code would also be meaningless. To do any useful analysis would require staff to compile the populations for each of these zip codes. We would then have to overlay the utilization data from all the HHAs licensed in the county to each zip code to look for alleged inadequacies in service delivery. This could be as many as 9 licensed HHAs for an unknown number of zip codes. Finally, we would then have to "roll up" these numbers to get the county totals since we don't license or review CONs by zip code.

This type of analysis is going far beyond the scope of the JAR. This sounds more like a special study that could be done in conjunction with an organization like the Home Care & Hospice Association to see what percent of referrals don't happen rather than JAR report. Staff does not support this recommendation for the reasons cited above.

COMMENT: The SCHA (page 191) commended staff and the SHPC for adopting a new methodology the projects a need for several additional home health agencies. However, some currently licensed agencies serve fewer than 50 patients annually, but since they hold the license for these counties new agencies cannot be approved. DHEC must find a way to address this problem. As health reform is implemented, this lack of service by some agencies will make it difficult for hospitals to discharge to the appropriate levels of care. While they do not propose a solution at this time, their Re-engineering Steering Committee is offering to assist the Department in addressing this issue during the next Plan development process.

STAFF RESPONSE: Accepted as information. Staff concurs that the issue of low-performing providers impacting the ability of other providers to access the market should be discussed during the development of the next Plan. We have a standard [#6, XII-13]

that requires an applicant to serve a minimum of 50 patients per county by the second year of operation or relinquish the license for those counties. Other than that, there is no mechanism in place to revoke the license of low volume providers.

COMMENT: The SC Home Care & Hospice Association (page 366) noted that nine of the 10 counties showing a need in the Draft would be at or exceeding the maximum number of agencies in the old methodology.

COMMENT: Bon Secours St. Francis Health System (page 358) noted that they have a HHA that currently is licensed for six counties. However, these counties are not inclusive of the hospital's entire service area. The ability to expand services is limited in both the existing and Draft Plans. A methodology that incorporates the needs of hospitals should be considered.

COMMENT: Spartanburg Regional Healthcare System (page 82) supports changing the methodology for calculating the need for HHAs. However, they noted difficulties in placing patients with other HHAs in other counties, particularly complex patients without a payer source. CMS has transitions of care demonstration projects in 14 states to identify best practices for reducing readmissions and home health is viewed as a critical component. Spartanburg Regional Healthcare System's HHA already participates in the HHQI initiative (XII-14). In order to impact these quality initiatives, patients must receive services within the same system of care to allow for better coordination and transitions of care. They recommend that hospital-based HHAs be given the ability to serve any inpatient discharged from their hospital or health system, regardless of the patient's county of residence.

STAFF RESPONSE: Staff does not support this recommendation. These agencies would have to be licensed to serve a particular county before they could serve a patient residing there. There are currently 13 hospital-based HHAs in the state. The majority are licensed to serve one to three counties; Self Regional serves five counties. Under this proposal, these agencies would be allowed to provide care in any county that they had an inpatient discharged from. For a system like Palmetto Health, between Richland and Baptist that would literally give them carte blanche to serve the entire state if they chose to do so. It would be inconsistent to make other applicants rely on a need methodology and go through CON but allow hospital-based HHAs to serve whatever counties they receive patients from.

COMMENT: The SC Home Care & Hospice Association submitted a copy of the North Carolina HHA standards (pages 368-405).

STAFF RESPONSE: Accepted as information.

COMMENT: CarePro (page 2) supported putting higher weight on counties with large populations over age 65.

COMMENT: Visiting Nurses Association of Bamberg (pages 149) stated that the Projected 2010 Pop Age 75-99 column in the need methodology (XII-16) was inaccurate because the Georgia methodology on which it was based uses 65-79 and 80-99 age groupings. The Georgia ratios are 45 patients/1,000 for age 65-79 and 185 patients/1,000 age 80+. Therefore, the projections for the South Carolina 75-79 year old population were being calculated using a higher ratio than in Georgia's methodology. They re-ran the calculations (page 151) to develop a proposed adjusted ratio for SC ages 75-99 of 119.4 patients/1,000.

STAFF COMMENT: Staff recommends incorporating the VNA proposed revised calculations into the need methodology. The population projections provided for the Plan broke out the 65+ population figures into 65-74 and for 75-99 so that was what was used in the calculations.

COMMENT: Lynn Bailey (pages 28-29) commented on the evolving physician practice model changes. Greenville Hospital System is anticipated to employ more than half of all physicians practicing in the county, in some specialties controlling all providers. Her concern is the potential conflict of interest because of the influence the hospitals have on the business and economic side of physician practices. In particular, Standard 7 [**sic**] on page XII-13 requires an applicant to submit detailed letters from referring physicians citing the number of referrals they will make or the reasons the existing providers are inadequate [**Staff note**: this is actually Standard 3, not Standard 7]. Hospital-employed physicians are free to refer patients to any appropriate clinical provider, but they may be restricted from writing the required letters documenting those referrals if the employer owns a competing service. Because of this inherent conflict of interest, the standard requiring letters of support and the number of referrals should be removed. Applicants should be able to substantiate a reasonable level of utilization with other data sources and general letters of support.

COMMENT: CarePro Health Services (page 2) also commented about the potential conflict of interest when applicants are required to seek letters of support from physicians that are employees of an entity that owns a competing HHA. They requested that this standard be deleted.

STAFF RESPONSE: The practice of requiring physicians to quantify their support for a particular agency dates to at least the 1996 Plan. The standard requires physicians to state how many patients they currently referred to HHAs, how many patients they intended to refer to the proposed HHA they were supporting, and any problems they had in accessing care from the existing providers. This gives us a basis to determine the accuracy of their utilization projections and sources of referrals in their CON applications.

Hospitals purchasing physician practices has had little impact on home health until now because we have only approved two CONs in the past decade. With a potential change in methodology additional counties may become open for expansion. While it can be argued that it is now harder to obtain physician letters of support, staff does not

recommend deleting this standard. Physician letters are more meaningful to the Department than reams of signed petitions from the general public.

COMMENT: Visiting Nurses Association of Bamberg (page 150) noted that they are a non-profit agency that serves Medicaid and indigent patients, which they are able to support from their Medicare profit margin. For-profit agencies aggressively pursue the profitable areas of business but do little Medicaid and indigent work. This can significantly impact non-profits as they move into rural areas. They recommend having a high patient threshold for new agency approval or keeping the maximum number of agencies standard to protect services to Medicaid and indigent patients.

COMMENT: Roper St. Francis Healthcare (page 67) stated that Standard 4 (XII-13) setting a minimum need of 50 additional clients to project need for a new agency is not justified. In the majority of counties, the existing agencies have the ability to meet that level of growth. They cite the experience of their Roper St. Francis Home Health Care increasing their utilization in Berkeley County from 346 clients in 2006 to 497 in 2007. They believe a minimum standard of 100, while still low, would be more appropriate.

COMMENT: VNA Bamberg (pages 4, 149, and 459) commented that the threshold of 50 patients for allowing a new HHA into a county was extremely low. Neighboring states use 250 patients as their standard. They recommended adopting at least a 200 patient threshold for an agency to enter a county. They believe that several counties that show a need in the Draft are being adequately served at this time [**Staff note**: the specific counties were not identified in their comments].

COMMENT: The SC Home Care & Hospice Association (page 366) recommends adopting a capacity threshold of 150 patients rather than the 50 in the Draft.

STAFF RESPONSE: The general consensus of the comments received appears to be that 50 patients is too low a target to justify the potential approval of an additional agency. The recommended minimum ranged from 100 to 200 patients. Staff will re-run the projections to show the potential results of each minimum level on the need methodology. As stated above, staff will also be attempting to incorporate 2009 utilization data, which could also impact the results of the need methodology, regardless of the capacity target chosen.

COMMENT: Roper St. Francis Healthcare (page 67) recommended that in cases where a county shows a need, a stated preference should be given to existing, licensed agencies to add a county as this will result in certain economies of scale and cost savings.

STAFF RESPONSE: Staff does not recommend accepting this comment. While there are certainly some start-up costs in establishing a new HHA, there is not the large capital outlay required for something like an ASF or hospital. In staff's opinion, it is not enough justification to give an existing agency(ies) an advantage in what will invariably become a review process with multiple competing applicants.

COMMENT: CarePro Health Services (page 2) felt that allowing Pediatric only HHAs while simultaneously counting the pediatric utilization in the proposed need methodology was double-counting a segment of the population.

STAFF RESPONSE: Staff disagrees with this assertion. There are no need projections in the Draft for Pediatric HHAs; it is left up to the applicant to justify such an agency. The need projections in the Draft (XII-16) were made using 2008 JARs data. For the 2008 JARs we didn't have any Pediatric-only HHAs. Interim got CONs to establish the only Pediatric HHA [**Staff note**: serving Berkeley, Charleston, & Dorchester Counties] and that agency was just licensed in 2010. The 2010 JAR will be the initial report from that agency. It is staff's intent to not include the utilization from Interim (and any subsequent Pediatric HHAs) when computing the need methodology, like we don't include data from other restricted agencies (ex. Alere and retirement communities). This would be for the next planning cycle and therefore is not relevant for the 2010-2011 Plan.

However, we had ~30 existing HHAs that reported treating at least some patients age 14 and under on its 2008 JARs. There is no prohibition against "regular" agencies treating children and obviously a number do. To not count this utilization would under-report both the total number of patients in need of service in a county and the workload of the existing agencies that currently treat these patients. Staff recommends rejecting this comment.

COMMENT: Interim Healthcare is the only provider currently licensed to provide pediatric-only home health [**Staff note**: they are licensed to serve Berkeley, Charleston and Dorchester Counties]. They requested that the restriction on Pediatric HHAs be changed from 0-14 years to either 18 or 21 years (page 424). The age limit of 14 was not explained in the 2008-2009 Plan and is confusing to explain to referral sources, payers and families. They believe that children would be better served to remain with the same team of providers until they reach the age of majority. They are concerned that transitioning to find another agency that will take the same child as they reach age 15 will be difficult. They also provided a number of guidelines from organizations such as the American Academy of Pediatric that define pediatrics as covering patients up to 18 or 21 years of age (pages 425-426).

COMMENT: MUSC Children's Hospital (page 409) supported the Interim request to raise the Pediatric HHA to 0-18 years of age, rather than the current 0-14 years.

COMMENT: The SC Home Care & Hospice Association (page 367) recommended leaving the standard unchanged at 0-14 years and have Department staff monitor the impact these new agencies will have on meeting the needs of this population.

STAFF RESPONSE: Interim raised the question as to why Pediatric HHAs are limited to patients 14 years of age? Since Medicaid covers up to age 18, why not allow them to serve 15-17 year olds?

Pediatric HHAs were added to the 2008-2009 Plan. The age issue was discussed at a meeting held in January 2009 with staff members from DHEC CON, Health Licensing, Certification, Home Health program areas, along with representatives from DHHS and the SC Home Care Association [**Staff note**: now the SC Home Care & Hospice Association]. The standard of patients age 14 and under was considered to be a reasonable compromise. The billing codes differ for this age group versus "adult" patients. There was also a desire to avoid impacting the many existing agencies that are currently serving teenage patients. Nurses are generally more comfortable with treating "young adult" patients versus children, so it is not as difficult for older teens to receive home health care through the existing agencies.

Staff is conflicted on this issue. There is logic to the statement that 15 year old patients are not significantly different enough from 14 year olds to require them to be transferred to another agency. At the same time, raising the limit to 18 or 21 can be seen as treating young adult patients that other HHAs are equipped to serve, subverting the intent of exempting Pediatric HHAs from the need methodology.

COMMENT: The SC Home Care & Hospice Association (page 367) recommended that the Total Visits and Visits/Patient columns in the table on XII-17 be deleted because the information could be misinterpreted by those unfamiliar with home health. The number of visits has been impacted by reimbursement, changes in chronic disease models and telemonitoring. In addition, the Community Care Retirement Community HHAs (those restricted to residential of a retirement community) operate under a different type of care model and cannot be compared with other HHAs in terms of the number of visits.

STAFF RESPONSE: Staff is willing to delete the columns of Visits/Patient and Total Visits from the table. Because of practice pattern changes, the visits data are less relevant than the total number of patients served. Staff also concurs that CCRC HHAs have significantly different utilization from other HHAs and this distorts the visits calculations. Looking at the 2008 utilization data (XII-18-21), the vast majority of the HHAs averaged between 15-25 visits/person, whereas several of the CCRC HHAs had over 100 visits/person. These distort the calculations, so staff recommends deleting those columns.